GUIDANCE MANUAL

FOR HAZARDOUS WASTE CATEGORIZATION

AND REVIEW PROGRAM

Report prepared by:

Science and Technology Branch
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Preamble

Regulation 347 under Ontario's Environmental Protection Act contains lists of hazardous industrial wastes, acute hazardous waste chemicals, and hazardous waste chemicals. There are provisions in Regulation 347 to continually update these lists. In other words, new wastes determined to be hazardous may be added to the lists, and site specific wastes may be reviewed and delisted from the initial generic listings, as being non-hazardous.

It is important to ensure that the categorization (listing) and review (delisting) decisions are based on uniform evaluations of consistent and comprehensive iniformation submitted in the applications. The waste categorization and review program has been designed to provide proper control of wastes that could adversely affect the human health and environment in Ontario. This program is explained in detail in two guidance manuals:

Volume A - provides details on addition of new hazardous wastes to the lists;

Volume B - provides details on the mechanism of review of specific non-hazardous wastes.

VOLUME A

GUIDANCE MANUAL

FOR CATEGORIZATION OF HAZARDOUS WASTES

IN REGULATION 347

REVISED DECEMBER 1993

ONTARIO
MINISTRY OF ENVIRONMENT AND ENERGY
SCIENCE AND TECHNOLOGY BRANCH

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(Volume A)

1.0 INTRODUCTION

1.1 Purpose of this document

In order to ensure proper handling and disposal of wastes, Regulation 347 under the Environmental Protection Act (EPA) of the Ontario Ministry of Environment and Energy (MOEE), provides definitions of hazardous wastes, and details the requirements for generators, carriers and receivers with respect to waste registration and manifesting.

The classification of hazardous wastes is achieved by a listing/testing approach, whereby wastes are defined as hazardous either by being listed in a Schedule or by possessing specified characteristics normally determined by test protocols.

The Regulation allows for review and continual updating of the Schedules. New wastes judged to be hazardous are added to the lists, while specific wastes from a particular facility determined to be non-hazardous can be reviewed (or delisted) for that particular facility only.

The purpose of this document is to provide details of the categorization (listing) process. A companion volume describes the evaluation procedures for potential review (delisting) of specific non-hazardous wastes from the lists.

1.2 Categorization (Listing) of hazardous wastes

Regulation 347 uses two steps to classify wastes as hazardous:

a) Testing of waste: using testing protocols defined in Regulation 347, the waste is tested for specific hazardous characteristics (i.e., ignitability, corrosivity, reactivity, leachate toxicity). A waste may also be defined as hazardous because it is regulated elsewhere (e.g. PCB waste in Regulation 362) or because of a specific property of concern (e.g. pathological waste, radioactive waste).

b) Listing of streams/contaminants: a specific industrial waste stream or a specific contaminant may be listed in Schedules 1, 2 or 3 of Regulation

347 because the waste presents a potential hazard to human health or the environment.

The Ontario Ministry of Environment and Energy (MOEE) has listed nearly 100 industrial waste streams as hazardous industrial wastes (Reg. 347 Schedule 1) and nearly 700 commercial products as acute hazardous and hazardous waste chemicals (Reg. 347, Schedule 2, Parts A and B). These wastes are listed because they typically exhibit one or more of the hazardous characteristics or because they contain contaminants that are known to be toxic or otherwise hazardous to human health and the environment. The purpose of listing a waste as hazardous is to ensure that the generator will identify and manage the waste properly. Schedules 1 and 2 were derived initially (in 1985) from similar lists prepared by the United States Environmental Protection Agency (USEPA).

The Ministry provides an ongoing mechanism for adding hazardous wastes to the existing lists. A request for listing a waste as hazardous does not require extensive documentation. However, the industry, the type of waste, the contaminants of concern and the current waste management practices must be identified as much as possible by the initiator. The Science and Technology Branch (STB) will review the request and will prepare a listing document if necessary.

Members of the public, industry or government may initiate the listing process by directing a request for the examination of an unlisted waste (believed to be hazardous) to the Science and Technology Branch of the MOEE.

2.0 LISTING CRITERIA UNDER VARIOUS LEGISLATION

The process of listing a waste as hazardous is based on the evaluation of the potential hazard of the waste on human health or the environment. The listing evaluation relies on toxicity criteria and environmental behaviour criteria of the waste. Such criteria have been defined by a number of government agencies in their legislation or policy. In an effort to provide clarification to the reader, a summary of the criteria are presented for the following agencies:

a) United States Environmental Protection Agency (USEPA), under the Resource Conservation and Recovery Act (RCRA);

b) Environment Canada, Environment Protection Service (EPS), under a Federal/Provincial/Industrial Working Group on Criteria and Lists;

c) Ontario Ministry of Environment and Energy (MOEE), under the Municipal/Industrial Strategy for Abatement (MISA) program: development of criteria for the Effluent Monitoring Priority Pollutants List (EMPPL). Although these criteria do not identify hazardous wastes, they, however, set priority on contaminants in a waste.

2.1 RCRA listing criteria

In summary, the RCRA listing criteria are defined in terms of:

(a) Four hazardous characteristics (ignitability, corrosivity, reactivity and leachate toxicity);

(b) Lethal toxicity (fatal to human);

(c) Toxicity leading to serious irreversible illness (e.g. mutagenicity, teratogenicity, carcinogenicity);

(d) Environmental behaviour of the contaminants, specifically in terms of their potential for:

- Migration
- Persistence
- Bio-degradation/bio-accumulation
- Historical and present waste management practices.

Details of the RCRA listing criteria are presented in Appendix I.

2.2 EPS hazardous waste criteria

An Environment Canada task force developed criteria for definition of hazardous wastes (EPS, 1985). Hazardous wastes are defined in terms of either dangerous goods listed in the Regulations under the Transportation of Dangerous Goods Act (TDGA) or criteria used in describing hazardous goods (Classes 1 to 9).

The TDGA criteria are similar to RCRA criteria for definition of hazardous characteristics (i.e. ignitability, corrosivity, reactivity and leachate toxicity). Additional classes in TDGA include

infectious material (Class 6.2) and radioactive material (Class 7).

Long-term and other toxicity criteria (e.g. carcinogenicity) are also addressed in TDGA by either listing or assigning the waste to Class 9.3. Details of the EPS hazardous waste criteria are presented in Appendix I.

2.3 MISA's EMPPL Criteria

The Effluent Monitoring Priority Pollutants List (EMPPL) criteria have been developed for the identification and the hazard assessment of effluent contaminants in Ontario, as part of the MISA program. The EMPPL criteria are a subset of the MOEE's Vector Scoring System, developed by the Priority List Working Group (MOEE) and two consulting firms, and modified by the Standards Development Branch (SDB/MOEE). The Vector Scoring System contains a large number of parameters, some of which require extensive information about the contaminant. The System ensures that the toxicity and the environmental fate are systematically evaluated for any contaminant. In the EMPPL procedures, a contaminant is scored on a scale of 0 to 10, for the following parameters:

Environmental behaviour parameters:

a) Environmental mobility;
b) Environmental persistence;
c) Bioaccumulation.

Toxicity parameters:

a) Acute lethality;
b) Sub-lethality on non-mammalian animals;
c) Phytotoxicity;
d) Sub-lethality on mammals;
e) Teratogenicity;
f) Genotoxicity/mutagenicity;
g) Carcinogenicity.

Environmental exposure:

An assessment of human and environmental exposure is conducted based on the potential presence of a chemical in Ontario municipal and industrial effluents.

3.0 LISTING CRITERIA UNDER REGULATION 347

3.1 Current Situation

The initial listing of hazardous wastes in the Schedules of Regulation 347 relied on the background research carried out and compiled by the USEPA for its Resource Conservation and Recovery Act (RCRA), and is consistent with the Canadian Transportation of Dangerous Goods Act (TDGA).

While RCRA lists will continue to be monitored for any additions, such additions will be evaluated through the new MOEE listing criteria and procedures outlined in this manual before being added to the Schedules of Regulation 347. Of course, based on the evaluations, the Minister may decide not to proceed with a particular listing.

The listing process described in this document involves the preparation of a listing background document for the new waste. The background document provides an extensive review of the data on toxicity of the contaminant(s) in question and fully considers the impact of the waste on human health and the environment, prior to formulating a recommendation. As is required for documents supporting a cabinet submission, the economic impact of listing wastes is also examined during the preparation of the background document.

3.2 Listing Criteria

A waste can be listed in Regulation 347 if it contains contaminants in concentrations or quantities such that the waste is judged by the Ministry to be potentially hazardous to human health or the environment (which includes air, water, soil, and biota). The potential hazard is evaluated in terms of hazardous characteristics, environmental behaviour and toxicity criteria. These criteria represent the findings and conclusions of organizations and agencies identified in Section 2.0. These criteria represent the new approach of the Ministry regarding toxicity evaluation of wastes.

3.2.1 Hazardous Characteristics

One approach to identify hazardous wastes under Regulation 347 is to define them in terms of hazardous characteristics. Wastes are defined hazardous (section 1 of Regulation 347) if they are:

a) Ignitable
b) Corrosive
c) Reactive
d) Leachate toxic

Hazardous wastes can also be defined in terms other than hazardous characteristics (i.e. pathological, PCB and severely toxic wastes).

A waste which exhibits a hazardous characteristic may also be listed. The purpose of listing a waste based on hazardous characteristics is to simplify its identification as hazardous in the industrial sector and to define acceptable waste management practices. The definitions of the hazardous characteristics are detailed in Appendix II.

3.2.2 Environmental Behaviour

This second category of criteria includes environmental mobility, persistence, bio-accumulation, and environmental exposure. The scoring system is detailed in Appendix II.

Environmental Mobility

Environmental mobility refers to migration of chemicals through environmental media (i.e. air, water, soil, sediment and biota). Inter-media transport can either be observed during field/lab studies or estimated in simple mathematical models.

Environmental Persistence

Environmental persistence refers to the tendency of a chemical to resist degradation under environmental stresses. Substances can be naturally subjected to a variety of degradation processes: oxidation, hydrolysis, photo-degradation and bio-degradation. Persistence is usually expressed as the half-life, which is the time required for one-half of the original amount of the substance to be degraded to a simpler chemical.

Values of half-life for chemical persistence may vary from seconds to thousands of years. Short half-lives (e.g. less than a few days) generally indicate a low level of concern (i.e. no significant accumulation in

the environment). On the other hand, long half-lives (e.g. longer than several months) can lead to substantial exposure or accumulation in the food chain.

Bio-accumulation

Bio-accumulation refers to the tendency for a substance to accumulate in biological systems, or tissues of organisms. The Bio-Concentration Factor (BCF) is frequently used as an index for bio-accumulation. In the case of aquatic organisms, the BCF is calculated as the ratio of the concentration (wet-weight basis) of a substance in the organism (or tissue) to the concentration of the substance in the water. For organic substances, values of the BCF range from about 1 to more than 1 million. BCF data for vertebrates are more difficult to evaluate and, consequently, are much less available.

Environmental Exposure

Environmental exposure refers to the evaluation of the possible pathways through which the waste contaminant(s) can reach a receptor and adversely affect human health and the environment. Environmental exposure assessment requires knowledge of waste generation parameters (quantity, concentration, frequency) and existing waste management practices. Scenarios of waste mismanagement can be drawn from this information. The worst case scenario is usually retained in the exposure assessment.

3.2.3 Toxicity Parameters

Acute Lethality

Acute lethality refers to the rapid lethality of a chemical to terrestrial and aquatic animals.

Sublethal Effect, Plants

Sublethal phytotoxicity refers to sublethal (injurious) effects of chemicals on plants. Sublethal effects vary widely depending on the chemicals. The significance of the injury may relate to appearance, growth or yield, and longevity. These toxic effects are generally assayed in laboratories.

Sublethal Effects, Mammals

Sublethal mammalian toxicity refers to the potential long-term effects of chemicals on mammals, including humans as a priority, and are restricted to sublethal systemic effects, which do not include carcinogenic, mutagenic or teratogenic effects.

Sublethal Effects, Non-Mammals

Sublethal non-mammalian toxicity refers to the potential effects in non-mammalian species, both aquatic and terrestrial, of long-term exposure to chemicals. Toxicity is evaluated in terms of median effective concentration (EC_{50}), maximum acceptable toxicant concentration (MATC) or no - observable - adverse - effect concentration (NOAEC).

Teratogenicity

Teratogenicity describes the potential of chemicals to cause non-hereditary congenital malformations (birth defects) in mammalian offspring. Such effects are usually irreversible.

Mutagenicity

Mutagenicity or genotoxicity refers to the ability of chemicals to cause permanent alteration of the genetic material within living cells.

Carcinogenicity

Carcinogenicity describes the potential of chemicals to cause cancer. Some biological, physical and chemical agents can cause or promote cancer.

3.3 Application of Listing Criteria

The listing criteria, outlined in Section 3.2 and detailed in Appendix II, are applied to each contaminant found in the waste. The toxicity of a mixture of contaminants found in the waste must be assessed, experimentally or mathematically, before a

decision can be taken regarding the listing of such a waste.

Testing for hazardous characteristics is the first and simplest step. If the waste can be classified as hazardous based on hazardous characteristics, there may be enough justification to list the waste, especially so if the environmental exposure is of concern.

As a second step, the environmental behaviour and toxicity parameters are applied to the contaminant(s) of the waste, using an evaluation method derived from the Vector Scoring System. The objective of the Vector Scoring System (which was developed by a consultant and MOEE) is to systematically evaluate the environmental fate and toxicity of a contaminant. Each environmental behaviour and toxicity parameter is scored on a scale of 0 to 10 (10 indicating the highest level of concern).

To simplify the evaluation process, a screening process has been established. The Ministry has set, for each parameter, a concern scoring level which represents the current thinking on severity of affect or potential hazard in an environmental content (see Table 1). These levels are similar to EMPPL levels (set by MISA for effluent monitoring), except for exposure assessment and chronic toxicity (sublethal effects), where pathways and long term exposure of contaminants are of more concern in waste management. If the score of any of the parameters equals or exceeds the respective concern level, the waste is selected by the screening system to be assessed in more detail.

In the detailed assessment of the waste, the MOEE staff conduct a toxicity assessment using toxicity scores and an exposure assessment using environmental behaviour scores. Various MOEE standards may be used for comparison and, where needed, research may be carried out to develop the necessary standards. The exposure assessment will help identify the pathways and the attenuation of the contaminants migrating from the waste to the receptor. The toxicity assessment will evaluate the risk levels of adverse effects on health and the environment.

For situations where the waste contains numerous contaminants, the combined toxicity must be assessed. Toxicity tests may be conducted on a representative waste sample. However, this approach may be costly and time consuming. Unless synergistic effects of the

contaminants are documented, the combined acute lethality can be evaluated by using the following rule:

(a) if any one of the contaminants, present in the waste, is selected by the screening system by reason of mutagenicity or carcinogenicity, the waste may be listed. These types of toxicity do not have a threshold value that links the concentration to the effect.

(b) if any one of the contaminants present in the waste is not selected for listing based on the parameters included in (a) above, the waste may still be selected by the screening system based on acute lethality. The lethal level (LD_{50} or LC_{50}) of the contaminant in the waste is calculated as follows:

$$LD_{50} \text{ (contaminant in waste)} = \frac{LD_{50} \text{ (contaminant)} \times 100}{\text{Percent of total contaminants by weight}}$$

(c) if the toxicity of all contaminants in the waste are below concern levels, the combined toxicity must be calculated, using one of the following information (if available) in order of priority:

1) Toxicity data on the precise mixture of the contaminants found in the waste;

2) Toxicity data of similar contaminant mixture:

"similar contaminant mixture" refers to a mixture having the same contaminants but in slightly different ratios, or having several common contaminants, but lacking one or more components, or having one or more additional contaminants. The determination of sufficient similarity must be made on a case-by-case basis;

3) Toxicity data of contaminants with quantified interactions:

synergistic or antagonistic interaction between certain contaminants of the waste may be documented and quantified. If enough documentation on enough contaminants of the waste is available, the toxicity of the mixture may be assessed;

4) Toxicity data of contaminants with additivity rules. These rules will be specific to individual waste listing cases and will be derived from current findings on toxicity additivity.

TABLE 1

CONCERN LEVELS FOR TOXICITY SCORING

ENVIRONMENTAL BEHAVIOUR PARAMETERS	CONCERN LEVEL (a)
1. Environmental Mobility	≥7
2. Environmental Persistence	≥7
3. Bioaccumulation	≥7
4. Environmental Exposure	≥7
TOXICITY PARAMETERS	
5. Acute Lethality	≥6
6. Sublethal effects, plants	≥4
7. Sublethal effects, mammals	≥4
8. Sublethal effects, non-mammals	≥4
9. Teratogenicity	≥2
10. Mutagenicity	≥6
11. Carcinogenicity	≥2

(a) Details of the Vector Scoring System can be found in Appendix II.

4.0 LISTING PROCESS

4.1 Request for Hazardous Waste Listing

Requests for the listing of wastes as hazardous would normally come from regulatory agencies for health and environment, concerned organizations and the public at large. More specifically, the following organizations within the Ministry of Environment and Energy may be involved:

a) Staff of the Science and Technology Branch (STB);

b) Hazardous Waste Review Committee (HWRC);

c) Staff of the Program Development Branch (PDB) involved in hazardous waste management planning and policy development;

d) Staff of the Standards Development Branch (SDB);

e) Other MOEE task forces or committees involved in contaminant evaluation and classification (e.g., Regulation 347 Steering Committee, Regulation 347 Implementation Committee, etc.); and

f) Regional staff of MOEE.

Outside MOEE, other organizations, such as noted below, involved in health and environment protection, may identify contaminants to be considered for listing:

a) Provincial, interprovincial and federal task forces or committees (e.g. Waste Committee, Transportation of Dangerous Goods (TDG) Working Group of the Canadian Council of Ministers of the Environment (CCME)); and

b) Public interest groups and associations.

4.2 Procedures

Figure 1 illustrates the procedures for categorization (listing) hazardous waste in Regulation 347.

A request for listing may come from one of the parties identified in section 4.1 The Environmental Engineering Services Section (EESS) of the STB reviews the information and may require, if needed, clarification from the requesting party.

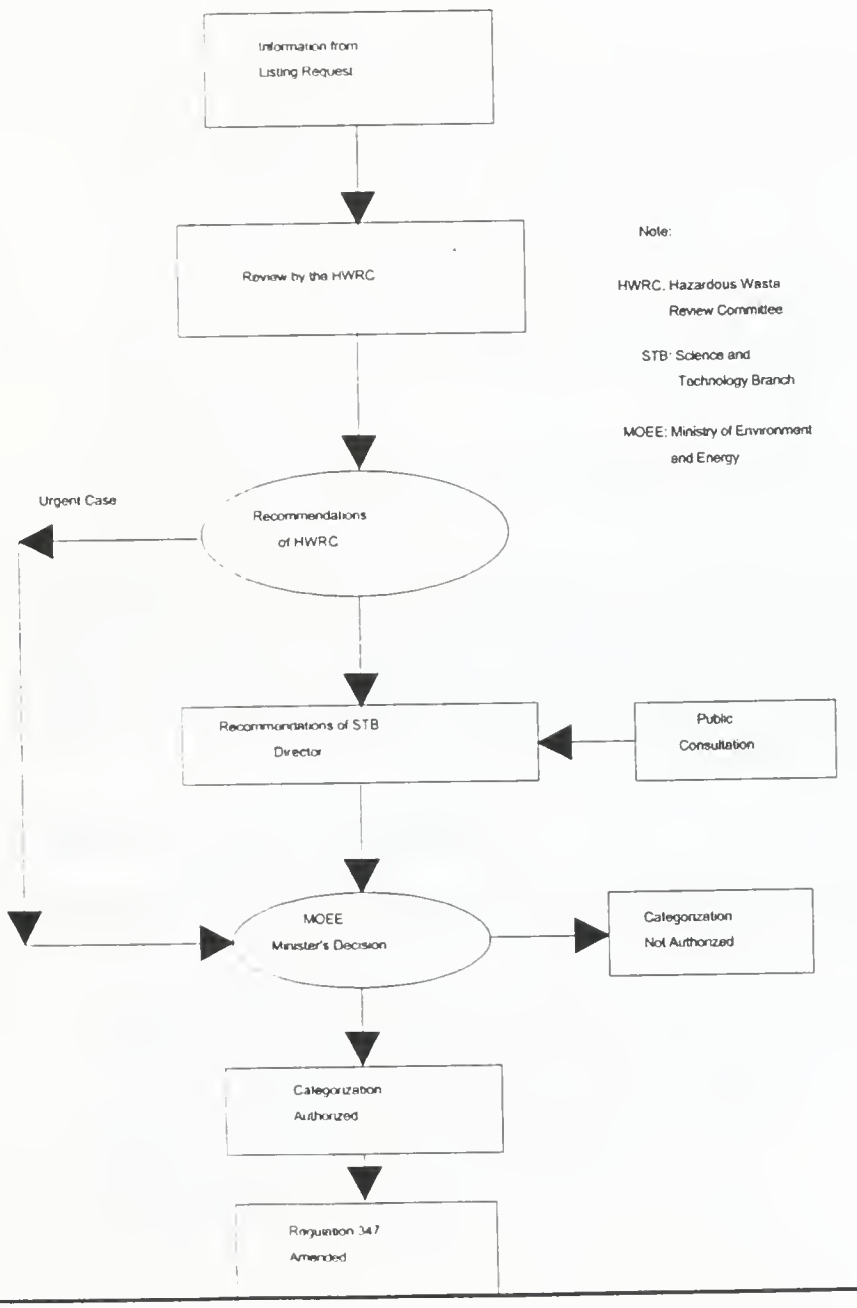
The EESS prepares a listing document which will identify the nature of the waste, the industrial sector generating the waste, the toxicity levels and proper waste management practices. The details of the nature and format of the listing document are presented in the following sections of this report. In the preparation of the listing document, assistance from environmental consultants, expert toxicologists or physicians may be required. Such experts may be found from senior staff of other Branches of MOEE or other ministries (Labour, Health, etc.). Consultations with the industrial sector in question and evaluation of the economic impact of the actions may also be initiated at this stage.

The categorization (listing) document is examined by the (internal) Hazardous Waste Review Committee (HWRC), consisting of members of each branch of MOEE and a member from the Ministry of Labour. The recommendations of this Committee are provided to the Director (STB), who forwards the document and the recommendations to the Minister's Office, through the ADM's (Assistant Deputy Minister) and DM's (Deputy Minister) Offices. If the Minister agrees with the listing (categorization) document and decides to authorize a listing in these Schedules of Regulation 347, necessary steps are taken to achieve this Amendment.

In urgent cases, the information can be forwarded from the STB staff directly to the Minister.

Figure 1:

Hazardous Waste Categorization (Listing) Process



5.0 PREPARATION OF LISTING DOCUMENT

5.1 Objective

The main objective of the listing document is to provide the technical basis for listing a waste under Regulation 347.

This requires that a number of issues be addressed:

a) Identification and detailed information about the process and the industrial sector responsible for the generation of the waste in question (including the quantity of waste generated);

b) Determination of the waste constituents, their concentration and their toxic effect levels;

c) Discussion of the benefits of listing this waste, compared to the existing waste management practices; and

d) Impact on the environment and/or human health, if waste not listed.

The listing document is later used by MOEE staff for reference in the interpretation and application of Regulation 347. The same document can also be used by either the waste generators or Ministry staff during a request for delisting of specific waste streams not identified during the listing process.

5.2 Content of Listing Document

A typical document will have, but may not be limited to, the following table of contents:

1. Summary of basis for listing
2. Description of industrial sector(s)
   - 2.1 Process description
   - 2.2 Waste generation and composition
3. Waste management practices
4. Hazardous properties of waste
5. References
6. Appendices (optional)

5.2.1 Summary of basis for listing

The purpose of the summary is to introduce the reader to the particular industrial sectors affected by the listing. Conclusions (i.e. the basis for listing) are summarized by indicating the human health and environmental concerns associated with the waste and the existing waste management practices.

5.2.2 Description of industrial sector(s)

A comprehensive review of the industrial sector identifies the general process of waste generation. Details of the production processes must be included in the description if they are related to the generation of the waste. Process and other variations will be taken into account in the documentation of the waste composition.

When possible, a comparison with similar industrial sectors, in other jurisdictions should be included. This information would be particularly useful in understanding industrial processes from which wastes are imported into Ontario.

5.2.3 Waste management practices

Existing waste management practices prevailing in the affected industrial sector(s) are reviewed in this section. In the absence of substantial and reliable information, the review may require the assistance of consultants under contract.

Waste management practices include quantity of waste generated, storage methods on site, means of transportation, and disposal methods. Detailed waste management incidents or problems should be included in the document to illustrate the need for listing a particular waste, because of the existing or anticipated impact on environment/human health.

5.2.4 Hazardous properties of waste

The hazardous properties of a typical waste from the industrial sector are assessed by using the criteria identified in section 3.2 of this document.

In more complex cases, an expert toxicologist may be contracted, generally by the Ministry, to prepare a study on health effects and risk assessment.

5.2.5 References

Any statements referring to studies or reports must be referenced in a manner similar to the one used in scientific papers or publications. This approach will allow for thorough review of the listing document by other scientific staff and committee members.

5.2.6 Appendices

Information, too lengthy to be incorporated in the main text, is included as appendices. This information is often necessary to support statements in the listing document.

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APPENDIX I: LISTING CRITERIA UNDER OTHER LEGISLATION

INTRODUCTION

For the purpose of clarity, a brief review of the existing listing criteria is presented in the following section.

I-1 RCRA listing criteria

Under this U.S. Public law "Resource Conservation and Recovery Act" (RCRA), a solid waste is listed as a hazardous waste if it meets at least one of the following criteria:

1. It exhibits any of the following hazardous characteristics: ignitability, corrosivity, reactivity, and EP (extraction procedure) toxicity;

2. It has been found to be fatal to humans in low doses, or in the absence of data on human toxicity, it has been shown in studies to have;

   a) An oral LD_{50} toxicity (rat) of less than 50 mg/Kg; or

   b) An inhalation LC_{50} toxicity (rat) of less than 2 mg/L (2,000 mg/m^3); or

   c) A dermal LD_{50} toxicity (rabbit) of less than 200 mg/kg; or

   is otherwise capable of causing, or significantly contributing to, an increase in serious irreversible or incapacitating reversible, illness (designated Acute Hazardous Waste);

3. It contains any of the toxic constituents listed in Appendix VIII of RCRA, unless it is concluded that the waste is not capable of posing a substantial hazard to human health or the environment when improperly managed (i.e. treated, stored, transported or disposed of), after considering any of the following factors:

   a) Nature of the toxicity of the contaminant;

   b) Concentration of contaminant in the waste;

   c) Potential migration of the contaminant to the environment under improper management scenarios;

d) Persistence of the contaminant;

e) Potential of degradation into non-harmful constituents;

f) Degree of bioaccumulation in ecosystems;

g) Plausible improper management scenarios;

h) Quantities of waste generated at sites, on regional/provincial/national basis;

i) Nature and severity of historical damage to human health and environment due to improper management of contaminants;

j) Action taken by other governmental agencies or regulatory programs based on human health/environment hazards from the contaminant; and

k) Other appropriate factors.

I-2 EPS hazardous waste criteria

A Federal/Provincial/Industry Task Force agreed on a general working definition for hazardous waste (Environmental Protection Service (EPS), 1985):

"HAZARDOUS WASTE: wastes which due to their nature and quantity are potentially hazardous to human health and/or the environment and which require special disposal techniques to eliminate or reduce the hazard."

Two main qualitative criteria were used by the Task Force to define "hazardous":

a) REACTIVITY: tendency of a waste to react or undergo change under specified chemical or physical conditions (i.e. properties such as explosive, ignitable, corrosive, interactive, bio-accumulative and radioactive).

b) TOXICITY: potential for a waste to cause damage to the structure or disturb the functions of an organism exposed to that waste (lethality, carcinogenicity, pathogenicity and genotoxicity etc.).

The Task Force further adopted the following criteria for classification of hazardous waste:

a) All substances currently listed as dangerous goods in the Regulations of the Transportation of Dangerous Goods Act (TDGA) and the list of generic and source-specific waste streams (listed in U.S. Federal Register, May 19 and July 16, 1980) are considered listed substances/waste streams under TDG Regulations (DOT, 1984);

b) Criteria used in describing hazardous properties for TDG classes 1 to 8 may be adopted for the designation of hazardous wastes:

Class 1: Explosives

Class 2: Gases

Class 3: Flammable liquids

Class 4: Flammable solids

Class 5: Oxidizing substances and infectious substances

Class 6: Poisonous substances and infectious substances

Class 7: Radioactive materials

Class 8: Corrosive substances

c) Criteria used in describing Class 9 wastes, include:

- chronic toxicity
- carcinogenicity, mutagenicity, and
- teratogenicity
- aquatic and phytotoxicity
- bio-accumulation
- persistence
- minimum quantity and threshold concentration

I-3 MISA'S EMPPL CRITERIA

The Effluent Monitoring Priority Pollutants List (EMPPL) criteria have been developed by the Standards Development Branch (SDB/MOEE) for the support of the Municipal / Industrial Strategy for Abatement (MISA) program. The purpose of the EMPPL program, derived from the Vector Scoring System, is to identify and assess the relative

hazard of contaminants present in municipal and industrial discharges into surface water in Ontario.

A scoring program called the Vector Scoring System, was developed by the MOEE Priority List Working Group. The objective of the Vector Scoring System is to identify chemicals of top priority for monitoring programs, research projects and development of guidelines and standards. The scoring system is based on the following criteria:

a) Environmental mobility (in air, water, soil, sediment and biota);
b) Environmental persistence;
c) Bio-accumulation;
d) Acute lethality;
e) Sub-lethal effects (on non-mammalians, plants and mammals);
f) Teratogenicity;
g) Genotoxicity/mutagenicity; and
h) Carcinogenicity.

Exposure Assessment

Once the environmental effects of the chemicals have been assessed, the assessment of potential human and environmental exposure must be done based on specific exposure standards. The MISA Priority Pollutant Task Force has developed the following criteria for ranking the environmental exposure:

a) Detected frequently (>50%) at sampling points;

b) Potentially present in Ontario

   - detected in natural environment and probable use/manufacture in Ontario;

c) Inferred to be present in process discharge and probable Ontario use/manufacture;

d) Possibly present based on literature information only;

e) Not present, based on analytical data and/or literature.

APPENDIX II: LISTING CRITERIA UNDER REGULATION 347

Introduction:

The listing criteria used in Regulation 347 are described in the following paragraphs. Details of the Vector Scoring System are also included.

II-1 Hazardous Characteristics

Ignitability

Under Regulation 347, a waste is considered ignitable if it meets one of the following critera:

1. It is a liquid, other than an aqueous solution containing less than 24 per cent alcohol by volume, and has a flash point less than 61°C as determined by any of the following test methods:

   ASTM D-56-79,
   ASTM D-3243-77,
   ASTM D-3278-78,
   ASTM D-93-79.

   Examples of ignitable liquid waste include ethanol, varsol, gasoline, petroleum distillates or paint thinners.

2. It is a solid and is capable, under standard temperature and pressure, of causing fire due to friction, absorption of moisture, or spontaneous chemical changes and, when ignited, burns so vigorously and persistently that it creates a hazard.

   An example of ignitable solid waste is magnesium dust.

3. It is an ignitable compressed gas as defined by Class 2, Division 1 of the Federal Transportation of Dangerous Goods Regulation (TDGR, 1985).

   Class 2, Division 1 gases are defined as substances that:

   a) Have a critical temperature less than 50°C or an absolute vapour pressure greater than 294 kPa at 50°C;

or

b) Exert an absolute pressure, in the cylinder, packaging tube or tank in which it is contained, greater than 275±1 kPa at 21.1°C or 717±2 kPa at 54.4°C.

and

(i) Are ignitable at normal atmospheric pressure when in a mixture of 13 per cent or less by volume with air,

or

(ii) Have a flammability range of at least 12.

Examples of ignitable compressed gases include methane (natural gas), butane or butane mixtures, and propane.

4. It is an oxidizing substance as defined by Class 5 of the TDGR (1985).

This includes substances such as chlorates, permanganates, and nitrates which readily yield oxygen to stimulate, or contribute to, the combustion of other materials. Substances that contain the peroxides -0-0- structure are also considered to be oxidizers.

Corrosivity

Wastes that are corrosive as defined in Regulation 347 by any of the following two criteria are hazardous:

1. if they are aqueous and have a pH less than or equal to 2.0 or greater than or equal to 12.5; or

2. if they are liquid and corrode steel (SAE 1020) at a rate greater than 6.35 millimetres per year at a test temperature of 55°C using the National Association of Corrosion Engineers (NACE) test method TM-01-69.

Reactivity

The reactive wastes definition presented in Regulation 347 encompasses a number of diverse properties. Generally, the intent is to include wastes that are

susceptible to violent/ vigorous reactions or are likely to generate toxic fumes.

Under Regulation 347, wastes are defined reactive if they:

1. are normally unstable and readily undergo violent change without detonating;

2. react violently with water;

3. form potentially explosive mixtures with water;

4. generate toxic gases, vapours or fumes in a quantity sufficient to present danger to human health or the environment when they are mixed with water;

5. contain cyanide or sulphide and when exposed to pH conditions between 2.0 and 12.5, can generate toxic gases, vapours or fumes in a quantity sufficient to present danger to human health or the environment;

6. are capable of detonation or an explosive reaction if subjected to a strong initiating source or if heated under confinement;

7. are readily capable of detonation or explosive decomposition or reaction at standard temperature and pressure; and

8. belong to a Class 1 explosive as defined by the TDGR. Schedule II List I of TDGR lists most Class 1 explosives.

Leachate Toxicity

Wastes that contain the contaminants listed in Schedule 4 of Regulation 347 such that they can leach out in concentrations that exceed 100 times the concentrations shown in the Schedule are hazardous. The Leachate Extraction Procedure, included as part of Regulation 347, is used to make this determination.

II-2 Environmental Behaviour Parameters

The criteria used here were adapted from the EMPPL criteria (MOE, 1987; MOE, 1988).

Environmental Mobility

This parameter describes the transport or mobility of chemicals through environmental media such as air, water, soil or biota. The environmental mobility of a chemical is

an important factor in evaluating its potential environmental and human health hazards.

Scoring Criteria

The scoring criteria for this element are based on data from monitoring studies or on estimates of environmental partitioning derived from using the Level 1 Fugacity Model for organic compounds developed by MacKay (Mackay, 1979; Mackay and Paterson, 1982, 1988). This model uses readily available physico-chemical data to estimate the percentage partitioning of an organic substance into several bulk media (air, water, soil and sediment) and sub-media (air, air-suspended particulates, water, water-suspended particulates, aquatic biota, soil-water, soil-solids, sediment pore-water and sediment-solids) based on an equilibrium steady-state model. The chemical parameters required by the model include vapour pressure, octanol:water partition coefficients, aqueous solubility, and molecular weight. The scoring criteria are set out below.

Fugacity models cannot handle inorganic chemicals. Decisions regarding inorganic chemicals should be based on monitoring data. However, if such data are not available, then inorganic compounds should be given the maximum score as inorganic ions will be widely distributed among the various compartments.

PARAMETER: Environmental Mobility

SCORE	CRITERIA
10	No single medium contains more than 80% of total amount released.
7	Any single medium contains more than 80-90% of total amount released.
4	Any single medium contains more than 90-95% of total amount released.
0	Any single medium contains > 95% of total amount released.

Environmental Persistence

This parameter describes the tendency for a chemical to persist in the environment. Substances in the environment can be subjected to a variety of processes including oxidation, hydrolysis, photodegradation and biodegradation. The net result of such processes may be expressed as the overall persistence of a substance in the environment. When quantified, persistence is usually expressed as the length of time required for one-half of the original amount of a substance to be degraded (i.e. the half-life).

Half-lives of chemicals may vary from seconds to thousands of years (ICF Inc., 1985). Short half-lives generally indicate a lower level of concern. For example, environmental releases of substances with half- lives of less than a few days often will not result in significant accumulation in the environment. Conversely, those with half-lives of several months or longer can lead to substantial exposure or accumulation in the food chain.

Scoring Criteria

The criteria for this parameter are based on half-life values or on general descriptors of persistence. If scores can be assigned using both quantitative and qualitative criteria, the higher score should be used.

If half-life data are available, they will usually pertain to specific media as opposed to general environmental persistence. This information provides an indication of levels of concern regarding specific media. In such cases, the medium providing the highest score will be used.

If persistence values have not been reported and cannot be estimated by using environmental models, other types of information may offer guidance in developing a score for this parameter. For example, structure-activity relationships (SARs) may provide general indications of persistence for relatively unknown substances structurally similar to more familiar substances.

PARAMETER: Environmental Persistence

SCORE	CRITERIA
10	Half-life greater than 100 days; OR designated as very persistent
7	Half-life of more than 50 days but less than or equal to 100 days; OR designated as moderately persistent.
4	Half-life of 10 days but less than or equal to 50 days; OR designated as slightly persistent.
0	Half-life of less than or equal to 10 days; OR designated as not persistent.

Bio-accumulation

This parameter describes the tendency for a substance to accumulate in biological systems. In the current context, the term bio-accumulation is intended to convey the ability of a substance to accumulate in the tissues of organisms. The tendency for certain groups or classes of chemicals to bio-accumulate is well documented.

One of the parameters frequently used to express bio-accumulation is the bio-concentration factor (BCF). Most BCF values pertain to fish or other aquatic organisms and are calculated as the ratio of the concentration of a substance in the organism (or some specific tissue) on a wet weight basis to the concentration of the substance in water at steady state (Veith et al., 1980). For organic substances, values of BCF range from about 1 to more than 1,000,000 (Lyman et al., 1982).

BCF values have also been determined for some terrestrial vertebrates but these data are less abundant and more difficult to locate than those for aquatic organisms. It is recommended for this assessment that data collection efforts first focus on BCF values for aquatic organisms.

The tendency of substances to bio-accumulate in tissue has been related frequently to hydrophobicity or lipophilicity (Veith et al., 1980). As a result, various regression equations have been suggested for predicting BCF values for aquatic organisms based on the octanol-water partition coefficient K_{ow} (ratio of concentration of contaminant in octanol to its concentration in water) and other physico-chemical properties. To date, those that use K_{ow} values have been the most widely investigated and most successful (Lyman et al., 1982; Geyer et al., 1984).

Scoring Criteria

Scoring criteria for this parameter are defined in terms of either BCF or log K_{ow}. The correlation between the two sets of criteria is based upon the following relationship developed from experimental data on 84 chemicals (Veith et al., 1980):

$$\log BCF = 0.76 (\log K_{ow}) - 0.23$$

Other equations have been developed based upon various groups of chemicals. When available, an equation which is more directly applicable to a substance being evaluated should be used.

The bio-accumulation of compounds with relatively high K_{ow} values is influenced by the degree to which a compound dissociates in water. Equations for estimating bio-accumulation that include a dissociation term have not been reported. For the scoring of this parameter, dissociation has not been included as a factor. Consequently, some organic substances may have higher scores than warranted. BCF values can be estimated only to within an order of magnitude using most of the correlations developed to date, and laboratory test situations are incapable of duplicating field situations (Lyman et al., 1982). Therefore, the consideration of dissociation effects may be unimportant for this evaluation.

If scores based on both the actual BCF and the K_{ow} can be determined, preference should be given to the measured BCF values rather than those estimated based on K_{ow}.

PARAMETER: Bio-accumulation

	CRITERIA	
SCORE	BCF	Log K_{ow}
10	>15000	>6.0
7	>500 - 15,000	>4.0 - 6.0
4	>20 - 500	>2.0 - 4.0
0	≤20	≤2.0

Environmental Exposure

The environmental exposure refers to the evaluation of the potential for a contaminant to reach a target (or receptor) through some possible pathways. The receptor includes either human or the environment in general (including mammals, non-mammals and plants). The most common pathway for a chemical to reach its target is either surface water, ground water or air. In some circumstances, the target may be exposed to direct contact with the waste.

The exposure assessment is very much a function of the waste management scenario that can be drawn for the waste in concern. To ascertain that scenario, existing waste management practices must be known, and potential mismanagement practices identified from information gathering and survey. The worst-case scenario is developed from the worst situation identified from existing waste management practices, and from other possible mismanagement practices. The environmental behaviour parameters can help assess the efficiency of the pathways to carry the contaminants from the disposal site to the target in concentrations or quantities sufficient to cause adverse effects on the target. Although there is potentially an attenuation of the contaminant concentration from the source (i.e. waste disposal site) to the receptor (human and biota), this estimated attenuation should reflect the worst conditions of attenuation. The total quantity of the contaminant deposited in the environment can also be a factor which will increase the score.

PARAMETER: Environmental Exposure

SCORE	CRITERIA
10	Under conventional waste management practices, the target is likely to be exposed to the contaminant at concentrations sufficient to adversely affect human health or the environment.
7	Under the worst-case scenario, the contaminant has a good potential to reach the target, either because of occasional mismanagement operations, or because of easy pathway between the contaminant source and the receptor.
4	Under the worst-case scenario, the contaminant has a low potential to reach the target and, if it does, it will be at low concentration due to large attenuation effects of the pathway.
0	Under the worst-case scenario, the contaminant has practically no potential to reach the target and affect, even lightly, human health and the environment.

II-3 Toxicity Parameters

Acute Lethality

This parameter describes the acute lethality of a chemical to terrestrial and aquatic animals. Non-lethal or reversible effects are not included.

Acute effects other than lethality (e.g. irritation, allergic reactions, general narcosis, etc.) are considered in other toxicity parameters. Criteria for phytotoxicity are also not included because of the difficulties in assessing lethality in plants.

Scoring Criteria

Scoring criteria for acute oral and dermal LD_{50} and inhalation and aquatic LD_{50} are similar to those utilized by the Transportation of Dangerous Goods Act (DOT, 1984) and the State of Michigan Critical Materials Registry (Michigan, 1979). Scores ranging from six to zero for oral and dermal LD_{50} are comparable to the extremely toxic to relatively non-toxic scales outlined in the literature (Hodge and Sterner, 1949; Gleason et al., 1977; Douli et al., 1980). The criteria for scores of 8 to 10 would identify chemicals with greater toxicity than those included in the scales referred to above. These more stringent criteria were adopted to ensure chemicals with extreme acute toxicity are clearly identified by the scoring system.

The scoring criteria for inhalation LC_{50} are derived from the oral LD_{50} criteria, assuming that a 60 kg individual respires 20 m^3 of air daily and that the contaminants have equal biological availability via the oral and inhalation routes of exposure. The aquatic toxicity LC_{50} data would usually be derived from 96-hour exposures.

Scoring ciriteria for this iparameter are as follows:

PARAMETER: Acute Lethality

Score	CRITERIA Oral LD_{50} mg/kg	Dermal LD_{50} mg/kg	Inhalation LC_{50} (mg/m^3)	Aquatic LC_{50} mg/L
10	≤0.5	≤0.5	≤1.5	≤0.1
8	>0.5-5	>0.5-5	>1.5-15	>0.1-1
6	>5-50	>5-50	>15-150	>1-10
4	>50-500	>50-500	>150-1500	>10-100

2	>500-5000	>500-5000	>1500-15000	>100-1000
0	>5000	>5000	>15000	>1000

Sublethal Effects, Plants

Sub-lethal effects on plants are highly variable depending on the toxicant. The relative significance of the injury or effect depends on the commodity and the use of the plant. These can be divided into three categories:

a) The appearance is important, but growth and yield are of much less importance. This is relevant for ornamentals, flower crops, leafy vegetables and fruit;

b) The impact on growth and yield are the most significant, and visible injury to the foliage, though unsightly, is of less importance. This is relevant for root vegetables, fruits and seeds;

c) There is no visible injurious effects but the longevity of the commodity has been altered. This is of greatest significance in flower crops and for stored fruit and vegetables;

The toxic effects can generally be assayed using short-term tests with indicator plants. The possible effects include a wide spectrum of responses: inhibition of germination, inhibition of seedling growth, growth abnormalities, reduction in either root or shoot growth, etc. Long-term tests with annual plants may be used to assess chronic effects such as decreased yield or decreased competitiveness (NAS, 1975).

The most commonly tested aquatic plants are algae and duckweed (Lemna minor) (EPA, 1978). Several test methods have been developed that use algae (for example, the U.S. EPA Algal Assay Bottle Test). Duckweed has been used to assess the effects of substances on aquatic macrophytes, (EPA, 1978).

Effects on the genetic make-up of the organism may be assayed using other short-term tests with plant material. These include gene mutations, DNA repair, primary DNA damage and chromosomal aberrations (Sandhu, 1980). Some examples of genetic mutation assays using plants are the measurement of chromosomal aberrations in root tip cells, the Tradescantia micronucleus assay (Sandhu, 1980) and the use of Arabidopsis for measuring the frequency of mutational events at the embryo stage (Redel, 1980).

Scoring Criteria

The score definitions for aquatic plants are very similar to those used in parameters which address sub-lethal effects on aquatic animals.

Various biomonitors have been used for different contaminants with each species displaying characteristic symptoms for a given pollutant. Some of these tests have been standardized to a substantial degree while others are only qualitative indicators. Standardized sampling methods have also been devised for substances that accumulate in vegetation and that are toxic to animals. Lichens are also used as accumulators or as indicators for presence (or absence) of a variety of contaminants.

Standardized tests have been reported for relatively few substances. In some cases, the scoring system can accommodate results expressed in concentration units (mg/L for substance in water, mg/m^3 for gaseous contaminants, and mg/kg for substances in the soil), but in most instances, the length of exposure is very important.

Soil extraction procedures are critical in determining the level of a contaminant, since the total amount of contaminant available by acid extraction may not be the same amount bio-available to the plant.

The scoring criteria for sublethal effects, plants are as follows:

PARAMETER: **Sublethal effects, plants**

		CRITERIA		
		Per cent of Growth Reduction		
SCORE	MEDIA	≤ 5 % (=NOAEC)	>5-50 % ($=EC_{50}$)	>50 %
10	water (mg/L)	<0.001	<0.01	<0.1
	air (mg/m^3)	<0.01	<0.1	< 1
	soil (mg/kg)	<0.01	<0.1	< 1
8	water (mg/L)	>0.001-0.01	>0.01-0.1	>0.1-1
	air (mg/m^3)	>0.01-0.1	>0.1-1	>1-10
	soil (mg/kg)	>0.01-0.1	>0.1-1	>1-10
6	water (mg/L)	>0.01-0.1	>0.1-1	>1-10
	air (mg/m^3)	>0.1-1	>1-10	>10-100
	soil (mg/kg)	>0.1-1	>1-10	>10-100
4	water (mg/L)	>0.1-1	>1-10	>10-100
	air (mg/m^3)	>1-10	>10-100	>100-1000
	soil (mg/kg)	>1-10	>10-100	>100-1000
2	water (mg/L)	>1-10	>10-100	>100-1000
	air (mg/m^3)	>10-100	>100-1000	>1000-10000
	soil (mg/kg)	>10-100	>100-1000	>1000-10000
0	water (mg/L)	>10	>100	>1000
	air (mg/m^3)	>100	>1000	>10000
	soil (mg/kg)	>100	>1000	>10000

Sublethal Effects, Mammals

This parameter describes potential long-term effects of chemicals in mammals. The effects are directed primarily at human health. Although the actual data used will largely be from laboratory animals, data from epidemiological studies will have priority. Other scoring systems (see Hushon and Kornreich, 1984) generally score chemicals for sub-lethal toxicity based on specific effects (e.g., separate scores for carcinogenicity, mutagenicity, teratogenicity, etc.), but most do not address systemic toxic effects. The toxic effects included in this parameter are restricted to sub-lethal systemic effects, but do not include carcinogenic, mutagenic or teratogenic effects since these are included in other parameters.

Scoring Criteria

If data on the effect of chemicals are available but at an unsuitable duration of exposure, the criteria should be corrected by an appropriate extrapolation factor to adjust for potential effects at the suitable exposure period. Criteria used in the development of scores for this parameter would be derived from sub-chronic (generally 90-day exposure) or chronic (usually 1 year or more) exposure studies in any mammalian species. If the data were derived from sub-chronic studies, it is recommended that the NOAEL (No - Observable - Adverse - Effect - Level) be divided by a 10-fold extrapolation factor (see FDA, 1982; Dourson and Stara, 1983). If the only data available involved even shorter term exposures, it is recommended that a 100-fold extrapolation factor be used. Considerable judgement will be required in the utilization of such extrapolation factors, considering issues such as the biological half-life of the chemical, the biological characteristics of the test system from which the data was derived, and knowledge of the usual consequences of the type(s) of adverse effects produced.

The scoring criteria for this parameter do not provide for differences in the type of toxic response observed. For example, if the effects associated with exposure are irreversible, the consequences of exposure are much more serious than if the effects are reversible, following cessation of exposure. For the purposes of this assessment, all effects are considered as equal, but details of differences in the severity of the effects should be carefully noted.

Examples of the various end-points included as chronic systemic effects are as follows:

a) Reproduction Toxicity
   - Adverse effects on reproduction as they affect the survival, development and well-being of the species, including interference with gonadal functions but excluding teratogenic effects.

b) General Toxicity
   - General gains and losses in body weight, behavioural alterations and increases in diseases secondary to chemical exposure.
   - Gross or microscopic alterations in tissues, indicative of disease from toxic events.
   - Adverse or deleterious effects on organ systems or functions, alterations in secretions of exocrine and endocrine glands, alterations in the brain and peripheral nervous systems.
   - Bio-chemical effects related to treatment.

If data are available on more than one of these effects, the effect occurring at the lowest exposure level in the most sensitive test system should be used in scoring. In addition, structure-activity relationships may provide estimates of the occurrence of chronic effects if data on the actual compound are lacking. Structure- activity relationships appear reasonably predictive for certain types of effects (e.g., narcotic effects). However, little predictive value is obtained for other effects using available methods. In the future, the accuracy of structure-activity relationships in predicting effects between different chemicals may improve.

The scoring system for this parameter is as follows:

PARAMETER: Sublethal Effects, Mammals

SCORE	CRITERIA[1] ORAL NOAEL mg/kg	INHALATION NOAEL mg/m^3
10	≤0.1	≤0.3
8	>0.1 - 1	>0.3 - 3
6	>1 - 10	>3 - 30
4	>10 - 100	>30 - 300
2	>100 - 1000	>300 - 3000
0	>1000	>3000

(1) Criteria are based on data from exposures of 90 days or more in duration. If data from studies of 28 to 89-days exposure are used, divide data values by 10. If data from studies of less than 14 days duration are used, divide data values by 100.

Sublethal Effects, Non-Mammals

This parameter describes potential effects from long-term exposures of non-mammalian species to chemicals. The effects-data may be expressed as median effective concentration (EC_{50}), maximum acceptable toxicant concentration (MATC) or no - observable - adverse - effect - concentration (NOAEC).

The most frequently reported data of these types are EC_{50} values for fish or other aquatic organisms such as daphnia. Associated with an EC_{50} value is the species studied, the endpoint(s) observed, and the duration of exposure. Common endpoints are immobilization, loss of equilibrium, effects on reproduction and other sub-lethal effects. As with other parameters, if different indicators of effects are available, the most sensitive would be used, unless scorer judgement indicates otherwise.

As with mammalian toxicity, duration of exposure is important to the interpretation of the results. For aquatic organisms, either full or partial life-cycle tests are preferred for the assessment of reproductive effects. Such tests may last as few as seven days or extend beyond a year depending on the life cycle. For terrestrial animals, periods of exposure usually last several months. For other types of effects, results from 96-hour exposures generally have more credence than shorter exposures. In addition, preference should be given to tests on freshwater species native or introduced to North America.

Scoring Criteria

Based on published results of the effects of many substances on aquatic organisms, the NOAEC values that appear in the score definitions are a factor of 100 lower than EC_{50} values (Konemann and Visser, 1983).

The scoring criteria for this parameter are as follows:

PARAMETER: Sublethal Effects, Non-Mammals

	CRITERIA				
	AQUATIC			TERRESTRIAL	
				SUBCHRONIC	CHRONIC
SCORE	EC_{50} (mg/L)	MATC (mg/L)	NOAEC (mg/L)	NOAEL (mg/kg)	NOAEL (gm/kg)
10	<0.02[1]	<0.002[1]	<0.0002[1]	<1[1]	<0.5[1]
8	<0.02[2]	<0.002[2]	<0.0002[2]	<2[2]	<0.5[2]
6	0.02 - <0.2	0.002 - <0.02	0.0002 - <0.002	1-<10	0.5-<5
4	0.2 - <2	0.02 - <0.2	0.002 - <0.02	10 - <100	5 - <50
2	2 - <20	0.2 - <2	0.02 - <0.2	100 - <1000	<50- <500
0	≥20	≥2	≥0.2	≥1000	≥500

(1) In different genera.
(2) In one genus.

Maximum Acceptable Toxic Concentration (MATC) values are 10 times lower than EC_{50} values.

Teratogenicity

This parameter describes the potential teratogenic effects of chemicals on mammalian systems. Toxic effects on reproduction in plants, non-mammalian and mammalian systems, as distinct from developmental defects, are described in the previous sections. The production of terata by exposure to chemical contaminants can seriously compromise the development and survival of offspring. Such effects are usually irreversible, although current understanding is that they have an exposure threshold (EPA, 1984).

The criteria for these effects are as outlined by the U.S. Environmental Protection Agency (EPA, 1984). Teratogenic effects include frank developmental malformations detrimental to the survival, future development, or well-being of newborn. They do not include developmental anomalies and aberrations that appear to be secondary to embryo-, feto- and material toxicity (see EPA, 1984; Khera, 1981). Many such effects are known to disappear as development proceeds (e.g., reversible delayed ossification of various parts of the skeleton, delayed development of specific organs, delayed eye opening, delayed vaginal opening, reduced body weight) (Khera, 1981). In some cases, exposure of pregnant females to chemicals can result in malnutrition due to decreased food intake. Malnutrition has been shown to delay embryo and fetal development, reduce birth weights and, in severe cases, produce irreversible neurological and metabolic abnormalities (EPA, 1984; Khera, 1984). These differences in the apparent severity between frank terata and minor developmental anomalies from chemicals are reflected in the scoring criteria for this element.

Scoring Criteria

Working from the assumption that teratogenic effects exhibit exposure thresholds (Khera, 1981; EPA, 1984), scoring criteria are based on gradations in exposure levels associated with effects. Since teratogenic effects are viewed as more serious than developmental anomalies as outlined above, higher scores are applied to chemicals showing evidence of frank teratogenicity. Chemicals producing developmental anomalies, as outlined previously, are assigned lower scores.

Duration of exposure is particularly critical in assessing teratogenic effects. To adequately assess the potential for such effects from a chemical, the exposure should occur at least through the period of organogenesis (e.g., usually from late in the first trimester through early in the third trimester of gestation). In addition, the levels of exposure studied should be sufficient to elicit a range of effects in the dams, from toxicity at the higher exposures to no-observable effects at the lower exposures (Grice et al. 1975; EPA, 1984; Khera, 1981).

The general requirements regarding route of exposure discussed earlier also apply to teratogenicity assessments.

The scoring criteria for this parameter are as follows:

PARAMETER: Teratogenicity

SCORE		CRITERIA
10	-	Teratogenic effects observed without overt maternal toxicity at maternal exposures ≤0.1 mg/kg/day during organogenesis, or at equivalent exposure[1].
8	-	Teratogenic effects observed without maternal toxicity at maternal exposures >0.1 - 1 mg/kg/day during organogenesis or equivalent exposure.
6	-	Teratogenic effects or developmental anomalies observed at maternal exposures >1 - 10 mg/kg/day during organogenesis or equivalent exposure.
4	-	Teratogenic effects or developmental anomalies observed at maternal exposures >10 - 50 mg/kg/day during organogenesis or equivalent exposure.
2	-	Teratogenic effects or developmental anomalies observed at maternal exposures >50 - 1000 mg/kg/day during organogenesis or equivalent exposure.
0	-	No terata or developmental anomalies observed, or observed only at maternal exposures ≥1000 mg/kg/day or equivalent exposure.

(1) The definition of equivalent exposure assumes that teratogenic effects by dermal or inhalation exposures would be similar to effects by oral exposures, at comparable doses. For inhalation exposures, it is assumed that a 60 kg adult respires $20m^3$ of air daily, which explains the factor of 3 between oral (or dermal) doses (mg/kg) and inhalation doses (mg/m^3).

Mutagenicity

This parameter describes the mutagenic and genotoxic potential of a chemical. Such effects in themselves are indicative of potential hazards of chemicals to health and the environment. In addition, the strength of such evidence is valuable in the interpretation of other potential hazards from chemicals (e.g., carcinogenicity).

Genotoxic or mutagenic effects on somatic or germ cells are considered equal potential hazards. Assessment of the potential for germ cell mutations requires specific tests (e.g., dominant lethal test, mouse heritable translocation assay) and results from such tests are not available for large numbers of chemicals. Chemicals, for which evidence of germ cell mutations are available, would receive higher scores, than chemicals with evidence of somatic mutations only.

Scoring Criteria

Higher scores are assigned to chemicals with adequate evidence of mutagenic/genotoxic effects derived from short-term tests. The primary objective is to score the potential of a chemical to produce such effects.

Chemicals producing direct mutagenic/genotoxic effects in the absence of overt toxicity are assigned the highest scores (e.g., the chemical or its activated metabolite(s) directly acts on genetic material to produce mutations or genotoxic effects). Clastogenic effects produced by chemicals that do not directly interact with genetic material are scored in the next category. Chemicals causing mutagenic or genotoxic effects indirectly by interfering with various cellular systems would receive lower scores. Scores of two or four should be assigned to chemicals having positive evidence from certain test systems but clear evidence of lack of effects in other test systems.

It is assumed that all test data will be derived under optimal experimental conditions (e.g., using validated test procedures, including appropriate S-9 metabolic activating systems, adequate control for unusual chemical/physical characteristics of the test chemicals).

PARAMETER: Mutagenicity

SCORE	CRITERIA
10	Conclusive evidence of mutagenicity or genotoxicity in recognized prokaryotic or eukaryotic test systems at exposure levels not producing overt toxic effects (*in vivo* and *in vitro* eukaryotic data are positive or are absent).
8	Evidence of clastogenic effects (general DNA damage, strand breaks, sister chromatid exchange), intercalations or crosslinks but no evidence of increased incidences of mutations or direct interactions with genetic material.
6	Does not interact directly with DNA, but interferes with cellular mechanisms such as DNA synthesis and DNA repair. Effects may be observed at exposure levels associated with overt toxicity unrelated to genetic effects.
4	Mutagen/genotoxin in prokaryotic systems only (i.e., data from eukaryotic test systems are negative).
2	Mutagen/genotoxin in *in vitro* systems only (i.e., data from *in vivo* systems are negative).
0	No evidence of mutagenic or genotoxic effects in a comprehensive battery of test systems.

Carcinogenicity

This parameter describes the potential of chemicals to cause cancer. There is general agreement that radiation, biological, physical and chemical agents can cause or promote cancer. In addition, the biochemical and molecular process of cancer development, as it is understood, is similar among mammalian species (NTP, 1984; OSTP, 1985). It is evident that the development of cancer is a mutli-stage

process involving interactions of agents with genetic material (the genome).

The induction of cancerous growths through interactions with the genome may occur directly through the induction of somatic mutations or indirectly by alterations in gene expression. A number of factors affect the occurrence of these events, including age, sex, genetic differences, strain and species differences, diet, dose rate, route of exposure, interactions with other agents and a variety of environmental conditions (NTP, 1984; OSTP, 1985). Furthermore, the production of these effects by a chemical may be by direct action of the chemical or its metabolites (e.g., direct acting, genotoxic carcinogens) or indirect through actions of the chemical on systems that secondarily produce cancerous growths (e.g., non-genotoxic or epigenetic mechanism). Although the detailed mechanism(s) of cancer production are not fully understood, it is evident that once the required modification in the genome occurs (known as initiation), the process is irreversible and self-propagating. A wide range of factors affect the initiation process, however, and many of these are believed to be reversible (IRLG, 1979; NTP, 1984; OSTP, 1985).

Although the exact mechanisms of the various stages of carcinogenesis are not fully understood, it is apparent that the events leading to the initiation of cells are dose-related. Once initiation has occurred, however, the subsequent development of tumours is independent of the exposure level (IRLG, 1979). This information is important to the scoring of the carcinogenic potential.

Based on this brief summary of what is known about the process of carcinogenesis (refer to IRLG, 1979, NTP, 1984 and OSTP, 1985, for more detailed discussions), the scoring criteria for this parameter differentiate between direct acting and indirect acting carcinogens. It is important that the scoring system not merely reflect the completeness of the data base because only a few chemicals have been adequately studied from an epidemiological point of view in human populations to assess their carcinogenicity. For many chemicals, epidemiological studies to assess their carcinogenic potential will never be conducted and complete reliance will have to be placed on animal bioassay data for their evaluation. If the data from animal bioassays are considered conclusive, "epidemiologically proven" and "potential human" carcinogens (i.e., positive in animal bioassays) are given equal weight in the scoring system.

Scoring Criteria

The following definitions of carcinogenicity are used in scoring this parameter (Tomatis, 1979):

- Evidence of carcinogenicity is positive when an increase in malignant tumours is caused in more than one species or strain, in multiple experiments with varying routes or levels of exposure or to an unusual degree with respect to type, site, incidence or latency period.

- Evidence of carcinogenicity is negative when no tumour induction is observed in at least two adequate and appropriate animal studies in different species or in both animal and epidemiology studies.

- Evidence of carcinogenicity is inconclusive when neither of the above two conditions apply, usually because the observations are inadequate, of unacceptable quality or excessively limited. Contradictory results from different test systems may also lead to an inconclusive assessment. Such conditions are recorded as either positive or negative for carcinogenicity.

There is a great deal of controversy regarding the potency ranking of carcinogens, particularly when attempting to denote the potency of a chemical to cause cancer in man from data derived from animal cancer bioassays. Animal bioassays utilize high exposure levels (known as the Maximum Tolerated Dose or MTD protocol, see NTP, 1984; OSTP, 1985). Judgements of carcinogenic potency based on information derived from such high levels of exposure may have little relationship to potencies at lower levels of exposure comparable to those found in the environment. Consequently, the basis for potency ranking is not considered adequately developed for use in a scoring system. However, if procedures for such ranking were found reliable, they would form a reasonable basis for the scoring of the carcinogenic potential of chemicals.

Important information to assist in the interpretation of animal cancer bioassay data vis-a-vis the potential of a chemical to cause cancer in humans can be derived from assessments of its mutagenicity/genotoxicity.

PARAMETER: Carcinogenicity

SCORE	CRITERIA
10	Direct acting human carcinogen or potential human carcinogen (based on animal bioassay data) with evidence of direct interactions with genetic material. Acts as an electrophile or direct alkylating agent, produces DNA adducts, induces cell transformation, etc.
8	Indirect acting human carcinogen or potential human carcinogen (based on animal bioassay data) with evidence that it does not interact with genetic material.
6	Carcinogenic in animal bioassay tests at levels of exposure shown to saturate enzymes involved in the metabolism of the compound or at exposure levels shown to cause histopathological lesions known to predispose animals to the development of cancers at sites where the lesions are observed (e.g., ATPAse deficient liver foci in rodents). Adequate evidence must be available, demonstrating that no interactions occur with genetic material and that the chemical does not induce cell transformation.
4	Positive tumorigenic agent (benign tumours) in humans or animals. Evidence of lack of interactions with genetic material must be available. Includes chemicals that act solely as promoters and those that cause cell transformation in vitro without evidence in other systems.
2	Tumorigenic in only one animal species and negative in other(s) (all studies considered adequate).
0	Not tumorigenic in an adequate animal bioassay in at least two species and must not interact with genetic material.

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